

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 585 Pharmacy

SPONSOR(S): Broxson

TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	6 Y, 7 N	Poche	Calamas
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

House Bill 585 permits a pharmacist, or a pharmacy intern, with proper certification and working under the supervision of a pharmacist, to administer the following:

- Influenza vaccine to an adult 18 years of age or older;
- Varicella zoster (chickenpox, shingles) vaccine to an adult 60 years of age or older;
- Pneumococcal vaccine to an adult 65 years of age or older; and
- Epinephrine using an autoinjector delivery system to an adult who is suffering an anaphylactic reaction.

The bill requires any pharmacist or pharmacy intern to be certified to administer the vaccines and epinephrine through a program approved by the Board of Pharmacy. The program must include 20 hours of continuing education classes regarding the safe and effective administration of the vaccines and epinephrine and the potential adverse reactions to the vaccines and epinephrine.

The bill amends the definition of “practice of the profession of pharmacy” to include the administration of certain vaccines and epinephrine autoinjection. The bill also makes other changes to s. 465.189, F.S., and s. 465.003, F.S., to reflect the addition of “pharmacy intern” and “vaccines and epinephrine autoinjection” to other provisions in the bill.

The bill does not appear to have a fiscal impact.

The bill provides an effective date of July 1, 2011.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Influenza and Vaccine Immunization

Influenza, commonly called the “flu,” is caused by the influenza virus that infects the respiratory tract. There are three types of influenza viruses: A, B and C. Human influenza A and B viruses are the cause of the seasonal outbreaks of the flu in the United States.¹ Human influenza C virus causes mild illness, but is not thought to cause seasonal outbreaks of the flu.²

The virus is typically spread from person to person when an infected person coughs or sneezes the virus into the air. Transmission rates are greatest for individuals in highly populated areas, such as in schools and residences with crowded living conditions. Influenza can cause severe illness and lead to serious and life-threatening complications in all age groups. Influenza is a major cause of illness and death in the United States- between 5 percent and 20 percent of the population gets the flu.³ Illness caused by influenza leads to over 200,000 hospitalizations and an average of 23,600 deaths each year.⁴ Ninety percent of these deaths occur among individuals aged 65 years or older.⁵

Influenza vaccine is the primary method for preventing the flu and its severe complications. Vaccines are effective in protecting individuals against illness or serious complications of flu, particularly those individuals who are at high risk for developing serious complications from the disease.

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention recommends that, when vaccine is available, persons in high-risk groups, including individuals age 65 or older, and people with chronic diseases of the heart, lung, or kidneys, diabetes, immunosuppression, or severe forms of anemia, should be vaccinated against the flu.⁶

Pneumococcal Disease and Vaccine Immunization

Pneumococcal disease is an infection caused by the bacteria called *Streptococcus pneumoniae*.⁷ Pneumococcal disease is the leading cause of serious illness in children and adults throughout the world.⁸ Bacteria can invade different organs of the body, causing pneumonia in the lungs, bacteremia in the bloodstream, meningitis in the brain, middle ear infections, and sinusitis.⁹ There are more than 90 known pneumococcal types; the ten most common types cause 62 percent of invasive disease worldwide.¹⁰ Each year in the U.S., there are 175,000 cases of pneumococcal pneumonia, more than

¹ Centers for Disease Control and Prevention, *Types of Influenza Viruses*, available at <http://www.cdc.gov/flu/about/viruses/types.htm>. (last viewed March 31, 2011).

² *Id.*

³ U.S. Department of Health and Human Services, *The Current Flu Situation*, available at <http://www.flu.gov/individualfamily/about/current/index.html>.

⁴ *Id.*

⁵ Centers for Medicare and Medicaid Services, *2010-2011 Immunizers' Question & Answer Guide to Medicare Part B & Medicaid Coverage of Seasonal Influenza and Pneumococcal Vaccinations*, available at www.cms.gov/AdultImmunizations/Downloads/20102011ImmunizersGuide.pdf.

⁶ Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, *Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza, Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, Vol. 60, No.1, January 21, 2011, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6001a1.htm?s_cid=rr6001a1_e.

⁷ National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, *Pneumococcal Disease In-Short*, available at <http://www.cdc.gov/vaccines/vpd-vac/pneumo/in-short-both.htm>. (last viewed March 31, 2011).

⁸ National Foundation for Infectious Diseases, *Facts About Pneumococcal Disease*, available at <http://www.nfid.org/factsheets/pneumofacts.shtml>. (last viewed March 31, 2011).

⁹ *Id.*

¹⁰ *Id.*

50,000 cases of bacteremia, and between 3,000 and 6,000 cases of meningitis.¹¹ According to the Centers for Disease Control and Prevention, invasive pneumococcal disease causes 6,000 deaths each year.¹²

Symptoms of pneumococcal infection, depending on the location of the infection, include fever, cough, shortness of breath and chest pain (pneumonia); stiff neck, fever, mental confusion, disorientation and sensitivity to light (meningitis); joint pains and chills (bacteremia); and a painful ear, a red or swollen eardrum, sleeplessness, fever and irritability (middle ear infection).¹³ Pneumococcal disease can result in long term damage, such as hearing loss, loss of a limb, and brain damage; pneumococcal disease can also result in death.¹⁴

The best way to protect against pneumococcal disease is through vaccination. The vaccination is very good at preventing severe pneumococcal disease, but it is not guaranteed to protect against infection and symptoms in all people.¹⁵ Persons aged 65 years or older are considered to be at high risk for pneumococcal disease or its complications. It is recommended that persons 65 years old or older be vaccinated against pneumococcal disease.¹⁶

Varicella Zoster Virus and Vaccine Immunization

Varicella Zoster virus (VZV) causes chickenpox and shingles. Chickenpox is a common childhood disease, characterized by a blister-like rash over the torso and face, itching, tiredness, and fever. Before a vaccine was developed, approximately 10,600 persons were hospitalized and 100 to 150 died each year in the U.S. as a result of contracting chickenpox.¹⁷ Since the development of a vaccine, the occurrence rate and severity of chickenpox has decreased.¹⁸

Shingles, a painful localized skin rash often with blisters, is caused by the reactivation of the VZV in the body of a person who contracted chickenpox, often years after suffering from the disease. Almost one out of every three people in the U.S. will develop shingles.¹⁹ There are 1 million estimated cases of shingles every year in the U.S., and half of those cases occur in persons over the age of 60.²⁰ The only way to reduce the risk of developing shingles is to get vaccinated.²¹

Anaphylaxis and the Use of an Epinephrine Auto-Injector Delivery System

Anaphylaxis is a severe, whole body allergic reaction to a chemical that has become an allergen.²² The human body releases chemicals during anaphylaxis that can cause shock, resulting in a sudden drop in blood pressure and the release of histamines, which restrict breathing.²³ Symptoms of anaphylaxis include a rapid, weak pulse, skin rash, nausea and vomiting.²⁴ Common causes include drug allergies, food allergies, insect bites or stings and exposure to latex.²⁵ The severely allergic population has

¹¹ *Id.*

¹² *Id.*

¹³ *See supra* at FN 7.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, *Varicella Disease Questions & Answers*, available at <http://www.cdc.gov/vaccines/vpd-vac/varicella/dis-faqs-gen.htm>. (last viewed April 1, 2011).

¹⁸ *Id.*

¹⁹ National Center for Immunization and Respiratory Diseases, Division of Viral Diseases, Centers for Disease Control and Prevention, *Shingles-Overview*, available at <http://www.cdc.gov/shingles/about/overview.html>. (last viewed April 1, 2011).

²⁰ *Id.*

²¹ National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, *Shingles-Prevention & Treatment*, available at <http://www.cdc.gov/shingles/about/prevention-treatment.html>. (last viewed April 1, 2011).

²² National Center for Biotechnology Information, U.S. National Library of Medicine, U.S. National Institute of Health, *Anaphylaxis*, available at <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001847/> (last viewed March 31, 2011).

²³ Mayo Foundation for Medical Education and Research, *Anaphylaxis*, available at <http://www.mayoclinic.cpm/health/anaphylaxis/DS00009>. (last viewed March 31, 2011).

²⁴ *Id.*

²⁵ *Id.*; *see also supra* FN 9.

increased significantly during that last ten years, with the current incidence rate estimated to be 49.8 per 100,000 person-years.²⁶

Anaphylaxis is an emergency situation that requires immediate medical attention. If anaphylaxis is not treated, it will lead to unconsciousness and possible death. Initial treatment of anaphylaxis includes the administration of epinephrine, also known as adrenaline, to improve breathing by relaxing muscles in the airways, stimulate the heart, and tighten the blood vessels to reduce swelling. Epinephrine is classified as a sympathomimetic drug, meaning its effects mimic those of the stimulated sympathetic nervous system, which stimulates the heart and narrows the blood vessels. It is available through a prescription from a physician.

Many individuals with severe allergies that have resulted in, or can result in, anaphylaxis carry epinephrine auto-injector delivery system. Common brands of the auto-injector delivery system include EpiPen and Twinject. The autoinjector delivery system consists of a syringe prefilled with an appropriate dose of epinephrine and a retractable needle to prevent injury or reuse, protected by a safety guard. There are two dosages available for the autoinjector delivery system- for children weighing between 33 and 66 pounds, the dosage is .15 mg; for children and adults weighing more than 66 pounds, the dosage is .30 mg.²⁷ When injected into the top of the thigh, epinephrine eases the symptoms of anaphylaxis until professional medical treatment is obtained.

Pharmacy Practice

Chapter 465, F.S., governs the practice of the profession of pharmacy. The Board of Pharmacy (Board) is authorized to adopt rules to implement the duties conferred upon it under the Florida Pharmacy Act.²⁸

Section 465.003(13), F.S., defines the “practice of the profession of pharmacy” to include compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent and proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. The practice of pharmacy also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and expressly permits a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients.

To become a licensed pharmacist in Florida, a person must apply to the Board to take the licensure examination. Prior to sitting for the examination, a person must submit satisfactory proof to the Board that he or she is 18 years of age or older, is a recipient of a degree from an accredited school or college of pharmacy in the U.S., and completed an internship program approved by the Board prior to graduation from a school or college of pharmacy.²⁹ A graduate of a school or college of pharmacy located outside of the U.S. must submit proof that he or she graduated from a 4 year undergraduate pharmacy program, demonstrated proficiency in the English language by passing both the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE), passed the Foreign Pharmacy Graduate Equivalency Examination approved by the Board, and completed a minimum of 500 hours of supervised work activity program within the state, under the supervision of a licensed pharmacist, and approved by the Board.³⁰ Every person seeking to take the licensure examination must complete the application form and remit a fee not to exceed \$100.³¹ Upon successful passage of

²⁶ Stephanie Guerlain, PhD, et al., *A comparison of 4 epinephrine autoinjector delivery systems: usability and patient preference*, NIH Public Access Author Manuscript, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892620/>, citing Decker WW, Campbell, RL, Luke A, et al., *The etiology and incidence of anaphylaxis in Rochester, Minnesota: a report from the Rochester Epidemiology Project*, J Allergy Clin Immunol., 2008;122:1161-1165.

²⁷ Dey Pharma, L.P., *EpiPen Prescribing Information*, available at <http://files.epipen.gethifi.com/footer-pdfs/patient-packaging-insert-pdf/Prescribing-Information.pdf>. (last viewed April 3, 2011).

²⁸ S. 465.005, F.S.

²⁹ S. 465.007(1), F.S.

³⁰ S. 465.007(1)(a)2., F.S.

³¹ S. 465.007(1)(a), F.S.

the licensure examination by an applicant, as determined by the Board, DOH shall issue a license to practice pharmacy to the applicant.³² A pharmacy license is renewed every two years by submitting an application and a renewal fee set by the Board not to exceed \$250.³³ Also, a pharmacist seeking renewal of his or her license must submit proof of completion of at least 30 hours of continuing professional pharmaceutical education during the two years prior to application for renewal.³⁴

To become a pharmacy intern, a person must be certified by the Board as enrolled in an intern program at an accredited school or college of pharmacy or certified as a graduate of an accredited school or college of pharmacy and not yet licensed as a pharmacist in Florida.³⁵ The Board may refuse to certify, or revoke the registration of, any intern for good cause, including acts or omissions deemed grounds for disciplinary action against licensed pharmacists included in s. 465.016, F.S.³⁶ The Board has developed detailed rules for the registration of pharmacy interns and internship program requirements for U.S. pharmacy students or graduates and foreign pharmacy graduates.³⁷

In Florida, a licensed pharmacist retains the professional and personal responsibility for any act performed as a registered pharmacy intern in the employment of the pharmacist and under his or her supervision.³⁸ Therefore, the pharmacist's professional liability insurance will likely cover the acts or omissions of the pharmacy intern. However, this rule does not shield a pharmacy intern from the possibility of being named as a defendant in a negligence lawsuit. Several insurance companies offer professional liability insurance policies designed for student pharmacists and pharmacy interns.³⁹

In 2007, the Florida Legislature passed the Pharmacist Kevin Coit Memorial Act (Act).⁴⁰ The Act amended s. 465.003(13), F.S., to include in the definition of the practice of the profession of pharmacy the administration of influenza virus immunizations to adults, pursuant to s. 465.189, F.S., which was also created by the Act. Section 465.189, F.S., sets out the terms and conditions under which a pharmacist may administer influenza virus immunizations to adults. Specifically, a pharmacist must enter into a written protocol with a physician licensed under chapter 458 or chapter 459 of Florida Statutes. The physician will serve as the supervisory practitioner and dictate, through the written protocol, which types and categories of patients to which the pharmacist may administer the influenza vaccine. A pharmacist must also maintain at least \$200,000 of professional liability insurance, and complete 20 hours of continuing education credits concerning the safe and effective administration of influenza virus immunizations.⁴¹

As of June 2009, all states allow pharmacists to immunize patients.⁴²

Immunization Administration in Florida

In addition to Florida-licensed medical physicians, osteopathic physicians, physician assistants, and nurses, paramedics may administer immunizations. Section 401.272, F.S., authorizes a paramedic to administer immunizations after his or her medical director has verified and documented that the paramedic has received sufficient training and experience to administer immunizations. Also, pharmacists may administer influenza virus immunizations to adults pursuant to s. 465.189, F.S.

³² S. 465.007(3), F.S.

³³ S. 465.008, F.S.

³⁴ S. 465.009, F.S.

³⁵ S. 465.013, F.S.

³⁶ *Id.*

³⁷ See Rule 64B16-26.2032, F.A.C. (U.S. pharmacy students/graduates); see also Rule 64B16-26.2033, F.A.C. (foreign pharmacy graduates).

³⁸ Rule 64B16-27.430, F.A.C.

³⁹ See, e.g., Pharmacists Mutual Insurance Company, at

<http://www.phmic.com/phmc/productlines/personal/Pages/IndividualPharmacistProfessionalLiability.aspx>

⁴⁰ Ch. 2007-152, Laws of Fla. (2007).

⁴¹ Rule 64B16-26.1031, F.A.C.

⁴² See map available at

<http://www.pharmacist.com/AM/TemplateRedirect.cfm?Template=/CM/ContentDisplay.cfm&ContentID=21623>.

Confidentiality of and Access to Patient Records

Chapter 456, F.S., specifies the general regulatory provisions for health care professions within the Department of Health (DOH). Section 456.057, F.S., deals with the confidentiality of, and patient's access to, medical records created by specified health care practitioners. "Records owner" is defined to mean any health care practitioner who creates a medical record following treatment of a patient, a health care practitioner to whom records are transferred by a previous treating health care practitioner, or an employee of a health care practitioner identified as the records owner. It is important to note that the patient is not considered the owner of his or her medical records.

For purposes of s. 456.057, F.S., the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities: certified nursing assistants; pharmacists and pharmacies; dental hygienists; nursing home administrators; respiratory therapists; athletic trainers; electrologists; clinical laboratory personnel; medical physicists; opticians and optical establishments; and persons or entities practicing under s. 627.736(7), F.S., relating to personal injury protection claims. The persons or entities specified in the section are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of s. 456.057, F.S., to maintain those documents required by the part or chapter under which they are licensed or regulated.

Confidentiality of and Access to Pharmacy Records

Section 465.017, F.S., provides that, except upon written authorization of the patient, a pharmacist is authorized to release patient prescription records only to the patient, the patient's legal representatives, and the patient's spouse if the patient is incapacitated, to DOH, or upon the issuance of a subpoena. The section also specifies other exceptions for the release of records maintained in a pharmacy relating to the filling of prescriptions and dispensing of drugs. Pharmacists are subject to discipline for using or releasing a patient's records, except as authorized by ch. 456, F.S., and ch. 465, F.S.

Effect of Proposed Changes

The bill authorizes a pharmacist or a pharmacy intern, with proper certification and working under the pharmacist's supervision, to administer:

- Influenza vaccines to adults 18 years of age or older;
- Varicella zoster vaccines to adults 60 years of age or older;
- Pneumococcal vaccines to adults 65 years of age or older; and
- Epinephrine using an autoinjector delivery system to an adult 18 years of age or older who is suffering an anaphylactic reaction.

The bill requires a pharmacist or pharmacy intern to complete 20 hours of continuing education classes approved by the Board of Pharmacy concerning the safe and effective administration of the vaccines listed in the bill and epinephrine autoinjection and potential adverse reactions to the vaccines and epinephrine.

A pharmacist or pharmacy intern who administers a vaccine or autoinjection must maintain and make available patient records related to the administration of a vaccine or autoinjection pursuant to the standards and requirements imposed on health care practitioners in s. 456.057, F.S. The records must be maintained for 5 years.

The bill amends the definition of "practice of the profession of pharmacy" to include the administration of certain vaccines and epinephrine autoinjection. The bill makes other changes to s. 465.189, F.S., and s. 465.003, F.S., to delete references to "influenza virus immunizations" and include the terms "pharmacy intern" and "vaccine or epinephrine autoinjection".

The bill expands the scope of practice of pharmacy to include the administration of three different vaccines and epinephrine using an autoinjector delivery system. Currently, pharmacists are permitted to administer the influenza vaccine. The bill allows pharmacists to administer two additional vaccines and epinephrine through an autoinjector delivery system to individuals over the age of 18 suffering an anaphylactic reaction. The bill also allows pharmacy interns, under the employ and supervision of a licensed pharmacist, to administer the same vaccines and epinephrine injection. Pharmacy interns have not been permitted to administer any treatment or medication directly to a person previously in Florida.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.189, F.S., relating to administration of influenza virus immunizations.

Section 2: Amends s. 465.003, F.S., relating to definitions.

Section 3: Provides an effective date of July 1, 2011.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Pharmacies that opt to allow its pharmacists and pharmacy interns to administer the vaccinations and epinephrine specified in the bill will realize a positive economic impact as customers seeking the vaccinations and epinephrine injection will pay the pharmacy to perform the task rather than seeking the vaccinations and epinephrine from some other health care provider.

D. FISCAL COMMENTS:

The DOH will experience a recurring increase in workload to certify pharmacy interns to administer vaccines and epinephrine following completion of the requisite number of continuing education classes. Also, DOH will incur non-recurring costs associated with amending its rules. According to DOH, current budget authority is adequate to absorb the costs associated with each activity.⁴³

⁴³ *Department of Health Bill Analysis, Economic Statement, and Fiscal Note for HB 585*, March 1, 2011, a copy of which is on file with the Health and Human Services Quality Subcommittee.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH has appropriate rule-making authority to amend its rules related to immunization vaccination administration.

C. DRAFTING ISSUES OR OTHER COMMENTS:

It is unclear whether a pharmacy intern must enter into his or her own written protocol with a supervisory physician to administer vaccines or epinephrine or if the written protocol of the supervising pharmacist will govern the administration of vaccines or epinephrine by the pharmacy intern. Also, the bill does not address whether or not a pharmacy intern will be required to carry his or her own professional liability insurance to administer vaccines or epinephrine.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES